PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 836-114PCT	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/CA 03/01716	International filing date *(day/month/year)* 12.11.2003	Priority date *(day/month/year)* 12.11.2002
International Patent Classification (IPC) or both national classification and IPC C07K14/47		
Applicant XENON GENETICS INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
09.06.2004	13.01.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Aslund, J Telephone No. +31 70 340-4393

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA 03/01716

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-50 as originally filed

Claims, Numbers

1-55 as originally filed

Drawings, Sheets

1/22-22/22 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☒ contained in the international application in written form.

   ☒ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 29-35 (no opinion with regard to industrial applicabilty)

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/ or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-40, 52-55
	No:	Claims	41-51
Inventive step (IS)	Yes:	Claims	35-40, 52-55
	No:	Claims	18-34, 41-51
Industrial applicability (IA)	Yes:	Claims	1-28, 36-55
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item III

Claims 29-35 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: DATABASE GENBANK [Online] 1 May 1999 (1999-05-01), MUZNY,D. ET AL.: "Homo sapiens 12p13.3 BAC RPCI11-388A16 (Roswell Park Cancer" XP002274931 Database accession no. AC004765

D2: WO 01/57187 A (BOYLE BRYAN J ;FORD JOHN E (US); HYSEQ INC (US); ZHOU PING (US); A) 9 August 2001 (2001-08-09)

Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 41-51 is not new in the sense of Article 33(2) PCT.

Nucleic acids with 100% sequence identity falling under the scope of claims 41-47 have been disclosed in D1 (see Nucleotides 131705-137266 (relevant for Seq Id no 6), Nucleotides 136417-139202,(relevant for Seq Ids 1,7, 9), Nucleotides 130245-143790 (relevant for Seq Id 12)).

Polypeptides falling under the scope of claims 48-51 have been disclosed in D2 (see polypeptide Seq Id no 104).

Claims 1-40, 52-55 are novel over the cited prior art.

Inventive step

Claims 18-28 relate to a method for identifying an agent that modulates the activity of an HSN2-encoded protein. The application provides no information regarding the activity of the HSN2-encoded protein. Thus, there appears to be not technical effect associated with the subject-matter of claims 18-28 and consequently an inventive step is denied.

Similarly, claims 29-34 relate to methods of treatments where an "effective amount" of a HSN2 modulator is used. The search report was restricted to antisense nucleic acids/ribozymes and antibodies, consequently examination is restricted accordingly. The application provides no information regarding the successful identification of a HSN2 modulator and there is no information regarding "effective amounts". Thus, there appears to be not technical effect associated with the subject-matter of claims 29-34 and consequently an inventive step is denied.

In view of the successful identification of the gene for linked to the hereditary disorder for HSAN II (Hereditary Sensory and Autonomic Neuropathy) provided by this application, an inventive step is acknowledged for the screening methods of claims 1-17, 35-40, 52-55

For the assessment of the present claims 29-35 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.